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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/648,816

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Michael R. Yeaman

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41552 7590 09/21/2009  
MCDERMOTT, WILL & EMERY  
11682 EL CAMINO REAL  
SUITE 400  
SAN DIEGO, CA 92130-2047

EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

09/21/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP\_Docket@mwe.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/648,816	<b>Applicant(s)</b> YEAMAN ET AL.	
	<b>Examiner</b> CHIH-MIN KAM	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-83 and 85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-69, 76 and 79 is/are rejected.
- 7) ☒ Claim(s) 70-75, 77, 78, 80-83 and 85 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed on August 24, 2009 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

#### ***Status of the Claims***

2. Claims 67-83 and 85 are pending.

Applicants' amendment filed on August 24, 2009 is acknowledged. Applicants' response has been fully considered. Claim 67 has been amended, and claim 84 has been cancelled. Therefore, claims 67-83 and 85 are examined.

#### **Withdrawn Claim Rejections-103(a)**

3. The previous rejection of claims 67-68 and 84 under 35 U.S.C. 103(a) as being unpatentable over Darveau *et al.* (U. S. Patent 5,409,898), is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 5-6 of the amendment filed August 24, 2009.

#### ***New Claim Objections***

4. Claim 67 is objected to because of the use of the phrase "and modified amino acids of the amino acids in said 7 amino acid core that retain antimicrobial activity, wherein...". It appears the phrase indicates the modified amino acids of the 7 amino acid core sequence retain antimicrobial activity. It is suggested to use the phrase "and a modified antimicrobial peptide with the amino acids in said 7 amino acid core sequence modified and retaining antimicrobial activity, wherein...".

#### ***Maintained Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1656

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and modified amino acids of the amino acids in the 7 amino acid core sequence that retain antimicrobial activity, wherein the modified amino acids are selected from the group consisting of N-epsilon-monomethyl lysine, beta branched amino acids, N-methylamino acids, alpha, beta-dehydro amino acids, and fluorinated amino acids; and an antimicrobial peptide comprising the sequence of SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which discloses an antimicrobial peptide comprising the amino acid sequence of SEQ ID NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising the amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in the present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising the amino acid sequence of SEQ ID NO:3, 10 or 13.

Art Unit: 1656

6. Claims 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 7,067,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and a modified antimicrobial peptide with the amino acids of the 7 amino acid core sequence modified and retaining antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3. This is obvious variation in view of claims 1-8 of the patent which disclose a context-activating peptide comprising the amino acid sequence of SEQ ID NO:1, 2, 3 or 4, which contains the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys, where SEQ ID NO:1 (33 amino acids), 2 (36 amino acids) and 4 (39 amino acids) of the patent comprises the instant sequence of SEQ ID NO:3 (18 amino acids) and the specification indicates SEQ ID NO:1, 2, 3, or 4 has less anti-microbial activity than the anti-microbial peptide, RP-1 (column 4, line 50-column 5, line 56). Both sets of claims cite an antimicrobial peptide comprising the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys or the instant SEQ ID NO:3. Thus, claims 67-69 in present application and claims 1-8 in the patent are obvious variations of an antimicrobial peptide comprising the amino acid core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys or the instant SEQ ID NO:3.

Response to Arguments

Applicants indicate they will submit a terminal disclaimers to the '769 and '621 patents under separate cover (page 5 of the response).

Art Unit: 1656

Applicants' response has been considered. Since a terminal disclaimer has not been filed, the rejection is maintained.

***Claim Objections***

7. Claims 70-75, 77, 78, 80-83 and 85 are objected to because the claims are dependent from a rejected claim.

***Conclusion***

8. Claims 67-69, 76 and 79 are rejected; and claims 70-75, 77, 78, 80-83 and 85 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

September 15, 2009